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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Yukihiko Uchi

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7055 7590 03/03/2011
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EXAMINER

ZALASKY, KATHERINE M

ART UNIT

PAPER NUMBER

1777

NOTIFICATION DATE

DELIVERY MODE

03/03/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No. 10/553,950	Applicant(s) UCHI ET AL.	
	Examiner KATHERINE ZALASKY	Art Unit 1777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,13,15,17-19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,13, 15,17-19, and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Status

1. **Claims 1, 13, 15, 17-19, and 21**, as amended 16 December 2010, are currently pending. **Claims 2-12, 14, 16, and 20** are cancelled.

Claim Interpretation

2. It is noted that the instant claims are directed to an apparatus. Therefore, regarding limitations recited in the claims which are directed to a manner of operating disclosed apparatus, it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states "Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim."

3. Additionally, a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

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Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

5. **Claim 21** is rejected under 35 U.S.C. §112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. **Claim 21** states that the distance between the individual hollow fiber membranes is gradually increased toward the end face. This limitation is already included in **claim 1**.

Duplicate claims

1. Claim 21 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). **Claim 21** states that the distance between the individual hollow fiber membranes is gradually increased toward the end face. This limitation is already included in **claim 1, at page 3, lines 2-3**.

Claim Rejections - 35 USC § 103

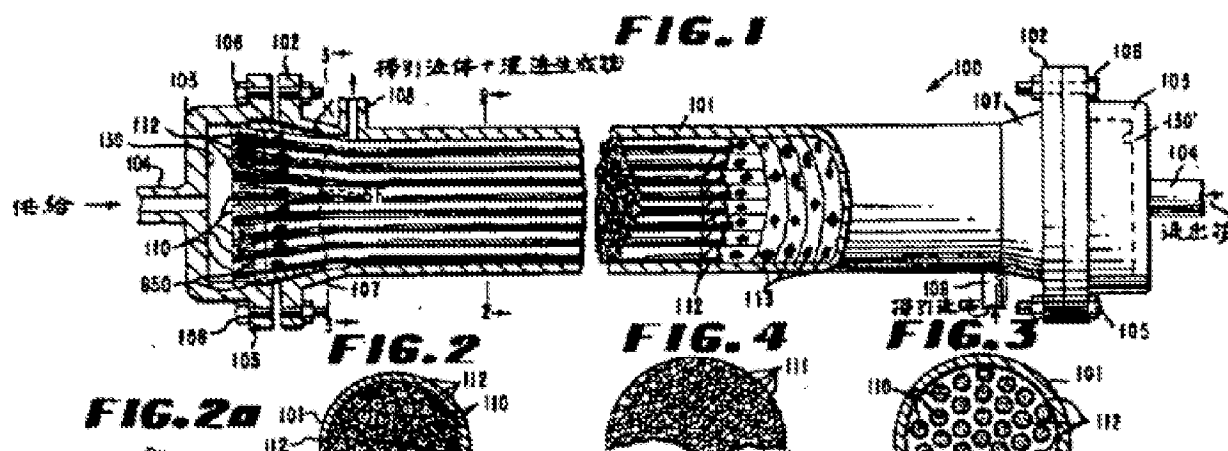
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. **Claim 1, 13, 15, 17 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 44-5526 in view of Fukasawa et al. (EP 0306613, "Fukasawa").

Regarding **claims 1 and 21**, JP 44-5526 discloses a hollow fiber membrane type fluid treatment device (Figure 1) comprising:

- a housing body portion of tubular housing containing a hollow fiber membrane bundle (Figure 1, housing 101, fibers 110)
- a first housing head portion (102) which is connected with one end of the housing body portion and a first connection port (108) which serves as a treatment liquid inlet
- a second housing head portion (102) which is connected with the other end of the housing body portion and a second connection port which serves as a treatment liquid outlet (108)
- first and second header caps (103) attached to the first and second housing head portions, respectively, and the first and second header caps having respective treatment target liquid connection ports (104)
- an inner surface of the housing body portion comprises a body straight portion in the center of the housing body portion (central portion of housing 101) and an end tapered portion provided at opposing ends of the housing body portion, the end tapered portion increasing in diameter toward an end face of the housing body portion (tapered portion on ends, 107)
- the hollow fiber membranes are arranged so that a distance between the hollow fiber membranes is gradually increased toward the end face of the

housing body portion as the hollow fiber membranes extend along a taper of the end tapered portions (Figure 1)

- opening ends of the hollow fiber membrane bundle being fixed to an inside of the housing by the resin layers and the opening ends of the hollow fiber membrane bundle facing the respective treatment target liquid connection ports (Figure 1, ports 104)
- the treatment liquid inlet and treatment liquid outlet being provided at a circumference of the hollow fiber membrane bundle (Figure 1, ports 108)



While the reference does not explicitly show a resin layer where the hollow fiber membrane bundle is fixed by using a resin composition, it is very well known in the art to use a resin plug near the header portion of a hollow fiber membrane module (as evidenced by Fukasawa, pg 6/L16-25). Therefore, it would have been obvious to one having ordinary skill in the art to use a resin material to fix the hollow fiber membranes in place near the headers since doing so amounts to nothing more than the use of a widely known and utilized technique for constructing hollow fiber membrane modules.

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While the reference does not explicitly disclose the ratio of the length of the body straight portion to the total length of the end tapered portion being between 0.7 to 20 and the ratio of the inner diameter of the end tapered portion on the end face side to the inner diameter of the body straight portion being more than 1 and not more than 3, since the instant specification is silent to unexpected results, it would have been obvious to one of ordinary skill in the art to change the lengths of the tapered and straight body portions as well as the diameters, since such a modification would have involved a mere change in the size (or dimension) of a component. A change in size (or dimension) is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). Where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device, and the device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device, *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

While the reference does not explicitly disclose the device wherein an angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion is greater than 0° and smaller than an angle defined by $\tan^{-1} \{(1/2) \cdot (d1-d4)/L4\}$. As the packing density and thus the efficiency of treatment fluid exchange are variables that can be modified, among others, by adjusting said angle, the precise angle would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made (see Fukasawa, pg 5,

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L25-28). As such, without showing unexpected results, the claimed angle cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the angle in the apparatus of modified Fukasawa to obtain the desired packing density and efficiency (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 223).

Regarding **claim 15**, JP 44-5526 discloses all of the claim limitations as set forth above, but does not explicitly disclose the device wherein the angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion is greater than 0.58° and smaller than an angle defined by $\tan^{-1} \{(1/2) \cdot (d1-d4)/L4\}$. As the packing density and thus the efficiency of treatment fluid exchange are variables that can be modified, among others, by adjusting said angle, the precise angle would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made (see Fukasawa, pg 5, L25-28). As such, without showing unexpected results, the claimed angle cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the angle in the apparatus of modified Fukasawa to obtain the desired packing density and efficiency (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the

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optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 223).

Regarding **claim 17**, JP 44-5526 discloses all of the claim limitations as set forth above. Regarding limitations recited in **claim 17** which are directed to a manner of operating disclosed device (e.g. “a urea clearance of 191 to 200 ml/min”), it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. *See Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

8. **Claims 1, 13, 15, 17, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 63-56044 in view of Fukasawa et al. (EP 0306613, “Fukasawa”).**

Regarding **claim 1**, JP 63-56044 discloses a hollow fiber membrane type fluid treatment device (Figure 2), comprising:

- a housing body portion of tubular housing (4) containing a hollow fiber membrane bundle (2)
- a first housing head portion which is connected with one end of the housing body portion and has a resin layer (3) where the hollow fiber membrane bundle is fixed by using a resin composition (3) and a first

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connection port (13) which serves as a treatment liquid inlet (Figure 2, upper end)

- a second housing head portion which is connected with a second of the housing body portion and has a resin layer where the hollow fiber membrane bundle is fixed by using a resin composition (3) and a second connection port (13) which serves as a treatment liquid outlet (Figure 2, lower end)
- first and second header caps (caps, 5) attached to the first and second housing head portions, respectively, and the first and second header caps having respective treatment target liquid connection ports (8, 9)
- an inner surface of the housing body portion comprises a body straight portion (straight center portion, 4) and an end tapered portion which increases in diameter toward the end face of the housing body portion (tapered ends shown in Figure 2)
- the hollow fiber membranes are arranged so that a distance between the hollow fiber membranes is gradually increased toward the end face of the housing body portion as the hollow fiber membranes extend along a taper of the end tapered portions (Figure 2, hollow fibers 2)
- opening ends of the hollow fiber membrane bundle being fixed to an inside of the housing by the resin layers and the opening ends of the hollow fiber membrane bundle facing the respective treatment target liquid connection ports (Figure 2, resin layer 3, facing openings 8, 9)

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- the treatment liquid inlet and treatment liquid outlet being provided at a circumference of the hollow fiber membrane bundle (Figure 2, openings 13)

While the reference does not explicitly disclose the device wherein an angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion is greater than 0° and smaller than an angle defined by $\tan^{-1} \{(1/2) \cdot (d1-d4)/L4\}$. As the packing density and thus the efficiency of treatment fluid exchange are variables that can be modified, among others, by adjusting said angle, the precise angle would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made (as evidenced by Fukasawa, pg 5, L25-28). As such, without showing unexpected results, the claimed angle cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the angle in the apparatus of JP 63-56044 to obtain the desired packing density and efficiency (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 223).

While the reference does not explicitly disclose the ratio of the length of the body straight portion to the total length of the end tapered portion being between 0.7 to 20 and the ratio of the inner diameter of the end tapered portion on the end face side to the inner diameter of the body straight portion being more than 1 and not more than 3, since

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the instant specification is silent to unexpected results, it would have been obvious to one of ordinary skill in the art to change the lengths of the tapered and straight body portions as well as the diameters, since such a modification would have involved a mere change in the size (or dimension) of a component. A change in size (or dimension) is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). Where the only difference between the prior art and the claims is a recitation of relative dimensions of the claimed device, and the device having the claimed dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device, *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

Regarding **claim 13**, JP 63-56044 discloses all of the claim limitations as set forth above. Additionally, the reference discloses the device wherein the tapered portion comprises a first tapered portion located on the body portion side (Figure 2, tapered portion near openings 13) and a second tapered portion located on the treatment liquid inlet side (Figure 2, tapered portions on the side opposing the openings 13). The reference does not explicitly disclose the angle of the first taper angle is smaller than the angle of the second taper angle.

Fukasawa discloses that an off-centered taper on the housing walls adds the benefit of increasing the distance between the side inlet port and the bundle of hollow fiber membranes, thereby enlarging the flow area of that part of the flow passage. This

annular flow passage allows incoming fluid to be more evenly distributed to the hollow fiber membranes (Figure 3, pg 4/L57 – pg 5/L2).

It would have been obvious to one having ordinary skill in the art at the time of the invention to use an off-centered tapered design on the ends of the housing in the apparatus of JP 63-56044, as taught by Fukasawa, since doing so will enlarge the flow area by the side openings, allowing incoming fluid to be more evenly distributed to the hollow fiber membranes.

Regarding **claim 15**, JP 63-56044 discloses all of the claim limitations as set forth above, but does not explicitly disclose the device wherein the angle formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion is greater than 0.58° and smaller than an angle defined by $\tan^{-1} \{(1/2) \cdot (d1-d4)/L4\}$. As the packing density and thus the efficiency of treatment fluid exchange are variables that can be modified, among others, by adjusting said angle, the precise angle would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made (as evidenced by Fukasawa, pg 5, L25-28). As such, without showing unexpected results, the claimed angle cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the angle in the apparatus of JP 63-56044 to obtain the desired packing density and efficiency (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the

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optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 223).

Regarding **claim 17**, JP 63-56044 discloses all of the claim limitations as set forth above. Regarding limitations recited in **claim 17** which are directed to a manner of operating disclosed device (e.g. “a urea clearance of 191 to 200 ml/min”), it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. *See Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

9. **Claims 18-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 44-5526 and Fukasawa et al. (EP 0306613, “Fukasawa”), as applied to **claim 1** above, and further in view of Kanno et al. (US 4,201,673, “Kanno”).

Regarding **claims 18-19**, JP 44-5526 discloses all of the claim limitations as set forth above. The reference does not explicitly disclose the device comprising baffle plates provided at positions corresponding to the treatment liquid inlet and the treatment liquid outlet of the tubular housing and interspatially from the inner circumference of the tubular housing over the entire inner circumference at a curvature almost along the inner circumference. Further, the reference does not disclose the device wherein the baffle plate gradually increases in diameter toward the end face of the housing.

Kanno discloses a dialyzer with hollow fiber membranes (abstract) which contains a baffle plate (annular rib 15) which increases in diameter toward the end of the housing (see Figures 2 & 3). Kanno teaches that a baffle plate may help avoid channeling and may improve efficiency by allowing fluid to flow over the outermost hollow fibers (C1/L45-60).

JP 44-5526, Fukasawa, and Kanno are analogous because both references are directed to hollow fiber membrane modules.

It would have been obvious to one having ordinary skill in the art at the time of the invention to add a baffle plate to the module of JP 44-5526, as taught by Kanno, since doing so may help avoid channeling, thereby improving the efficiency of the device.

10. **Claims 18-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 63-56044 and Fukasawa et al. (EP 0306613, "Fukasawa"), as applied to **claim 1** above, and further in view of Kanno et al. (US 4,201,673, "Kanno").

Regarding **claims 18-19**, JP 63-56044 discloses all of the claim limitations as set forth above. The reference does not explicitly disclose the device comprising baffle plates provided at positions corresponding to the treatment liquid inlet and the treatment liquid outlet of the tubular housing and interspatially from the inner circumference of the tubular housing over the entire inner circumference at a curvature almost along the inner circumference. Further, the reference does not disclose the device wherein the baffle plate gradually increases in diameter toward the end face of the housing.

Kanno discloses a dialyzer with hollow fiber membranes (abstract) which contains a baffle plate (annular rib 15) which increases in diameter toward the end of the housing (see Figures 2 & 3). Kanno teaches that a baffle plate may help avoid channeling and may improve efficiency by allowing fluid to flow over the outermost hollow fibers (C1/L45-60).

JP 63-56044, Fukasawa, and Kanno are analogous because both references are directed to hollow fiber membrane modules.

It would have been obvious to one having ordinary skill in the art at the time of the invention to add a baffle plate to the module of JP 63-56044, as taught by Kanno, since doing so may help avoid channeling, thereby improving the efficiency of the device.

Response to Arguments

11. To the extent that applicant's arguments filed 16 December 2010 are applicable to the newly presented rejections, they have been fully considered but they are not persuasive.

12. Arguments to the rejection under Fukasawa alone are moot as this rejection is no longer applicable to the amended claims.

13. Applicant argues that JP 44-5526 discloses that there are bundles of hollow fiber membranes; the distance between the sleeves increases. In this case, the distance between some individual hollow fiber membranes will be increasing, thus meeting the limitations of the claims.

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14. As stated previously, the Applicant has argued that the references do not disclose the details of **claim 1** because the optimization of the angles in the reference, as provided by the rejection above, is improper. The Applicant states that they have significant results by using an angle as defined by the claim, thus the optimization would be non-obvious. However, the results of presented in the instant specification do not support the full range of the claim limitation and do not support that the improvement was unexpected. The comparative examples in the instant specification are hollow fiber membrane modules having no angle at all; there is not a single comparative example presented that shows the criticality of the particular range of angles claimed. The references applied all have angled sides, the angle may be optimized based on the properties discussed in the rejection. Where is the evidence which supports that the results of the instant invention are unexpected? Has the problem of the fluid taking a short path through the module been an unsolved problem facing the area of art? Where is the evidence which supports that the particular range of angles claimed is significant? The current evidence presented in the specification merely shows that a module with angled ends has better results/separation properties than a module which is completely straight.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE ZALASKY whose telephone number is (571) 270-7064. The examiner can normally be reached on 7:30am - 4:00pm Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. Z./

Examiner, Art Unit 1777

17 February 2011

/Vickie Kim/

Supervisory Patent Examiner, Art Unit 1777